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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/809,021	03/16/2001	Hubert Metzner	06478.1452	5147
22852	7590	11/28/2003	EXAMINER	
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 1300 I STREET, NW WASHINGTON, DC 20005			MELLER, MICHAEL V	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 11/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/809,021

Applicant(s)

METZNER ET AL.

Examiner

Michael V. Meller

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-38 is/are pending in the application.
- 4a) Of the above claim(s) 20-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 18, 19, 35-38 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

The restriction requirement is maintained for the reasons of record.

Claim Rejections - 35 USC § 112

Claims 18, 19, 35-38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising thrombin, benzamidine or p-aminobenzamidine, nacl, cacl, l-histidine, mannitol, na, succinate, na lactate, l-arginine, does not reasonably provide enablement for any and all inhibitors of thrombin, sugars, sugar alcohols, amino acids, etc.. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The specification as filed, is enabled for a composition comprising thrombin, benzamidine or p-aminobenzamidine, nacl, cacl, l-histidine, mannitol, na, succinate, na lactate, l-arginine, but is not enabled for any and all inhibitors of thrombin, sugars, sugar alcohols, amino acids, etc...

The art of biotechnology is a highly unpredictable art and it would be an undue burden for one of ordinary skill in the art to test any and all inhibitors of thrombin, sugars, sugar alcohols, amino acids, etc..to see if they could perform the disclosed use.

Applicant has only shown in their examples that a composition comprising thrombin, benzamidine or p-aminobenzamidine, nacl or cacl, l-histidine, l-arginine, mannitol, na succinate, or na lactate even works for the disclosed use. With only knowing these specific components it is clear that such broad claims are not enabled by the instant specification when one of ordinary skill in the art is only given the particular components to produce a composition able to perform the disclosed use.

Applicant argues that the benzamidine is taught in the art, but the claims are not limited to benzamidines. Sturzebecker was considered and does show benzamidine based inhibitors but it does not teach any and all noncovalently binding inhibitors of thrombin activity. Hauptmann shows some benzamidine-type thrombin inhibitors but does not show any and all noncovalently binding inhibitors of thrombin activity. How can one of ordinary skill in the art be able to ascertain what other inhibitors are contemplated when applicants only give guidance for this one type of inhibitor (benzamidine). The art of biotechnology is highly unpredictable and to know which noncovalently binding inhibitor of thrombin activity could be just about anything. Further, it is not even clear how one would even go about trying to figure out what substances even fall within this category.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 18 and 35-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Hanada et al.

Applicants argue that the claims recite that the thrombin preparation is suitable for therapeutic purposes and that the use of trialkylphosphates does not anticipate the claims.

The examiner has already addressed the argument concerning the therapeutic use. First this statement is subjective and relative. The thrombin is used for therapeutic use as has been shown on the record. The use of trialkylphosphates is not a problem since applicant also teaches to use virus inactivation, see page 5 of applicant's own specification, see also the examples in the claims with special attention drawn to the use of Planova. How can applicant state that a compound is added to kill viruses and then in their method also kill viruses with a compound/membrane. The fact of the matter is the reference reads on applicant's invention and thus the rejection is maintained.

Applicant's arguments concerning the trialkyl phosphate treatment are also not well taken since it is clear in the reference that they use the thrombin use for therapeutic purposes too. In col. 1, of Hanada they recognize the importance of the use of thrombin. The whole patent is drawn to producing a therapeutic composition of thrombin since the composition is going to be used for clinical purposes. Thus, Hanada does teach a therapeutic composition of thrombin.

Claims 18, 35, 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Allary et al. or Lorne et al.

The references each teach that benzamidine and thrombin are together in a composition.

Applicant argues that these references also do not show that the thrombin is therapeutic but why else would Allary and Lorne use the thrombin in a biological/fibrin glue unless it had therapeutic activity. It is inherent that the references teach a thrombin with therapeutic activity since they teach that the compositions will be used for biological purposes.

Claim Rejections - 35 USC § 103

Claim 38 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hanada et al.

Applicant argues the same arguments as have been addressed above.

Claims 18, 19 and 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanada et al. taken with Brezniak et al. and Altshuler.

Applicant argues the same arguments as have been addressed above.

Claims 18, 19 and 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allary et al. or Lorne et al. taken with Hanada et al., Brezniak et al. and Altshuler.

The teachings of the references are above. Allary and Lorne show that thrombin and benzamidine are well known in the art to be together for making biological glue as applicants also do.

Hanada teaches the other components in the formulation and their use is also for thrombin production. Brezniak and Altshuler are of record.

Claims 18, 19 and 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanada et al. taken with Allary et al. or Lorne et al. and further with Brezniak et al. and Altshuler.

The teachings of the references are above.

Allary and Lorne show that thrombin and benzamidine are well known in the art to be together for making biological glue as applicants also do.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 703-308-4230. The examiner can normally be reached on Monday thru Friday: 9:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 703-306-3220. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A handwritten signature in black ink, appearing to read 'M. V. Meller', with a long horizontal stroke extending to the right.

Michael V. Meller
Primary Examiner
Art Unit 1654

MVM